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510(K) SUMMARY

JUN 2 1 2013

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92(c).

The assigned 510(k) number is:

1. Submitter:

Shenzhen Mindray Bio-medical Electronics Co., LTD Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

Tel: +86 755 8188 5658 Fax: +86 755 2658 2680

Contact Person:

Wu Zicui Shenzhen Mindray Bio-medical Electronics Co., LTD Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

Date Prepared: February 01, 2013

2. Device Name:

DP-20 Digital Ultrasonic Diagnostic Imaging System DP-30 Digital Ultrasonic Diagnostic Imaging System

Classification

Regulatory Class: II Review Category: Tier II

21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (IYN)

21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (IYO)

21 CFR 892.1570 Diagnostic Ultrasound Transducer (ITX)

3. Device Description:

The DP-20 and DP-30 Digital Ultrasonic Diagnostic Imaging System are general purpose, portable/mobile (with mobile ultrasound trolley), software controlled, ultrasonic diagnostic systems. Its function is to acquire and display ultrasound data in B-Mode,

M-Mode, or their combined mode B+M Mode. The systems are Track 3 device that employs an array of transducers including linear array and convex array. The frequency range of DP-20 is approximately 2.0 MHz to 10.0 MHz and that of DP-30 is approximately 2.0 MHz to 12.0 MHz.

4. Intended Use:

The Digital Ultrasonic Diagnostic Imaging System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, pediatric, small organ(breast, thyroid, testes), neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), cardiac(adult, pediatric), peripheral vascular and urology exams.

5. Comparison with Predicate Devices:

DP-20 and DP-30 Digital Ultrasonic Diagnostic Imaging System is comparable with and substantially equivalent to these predicate devices:

Predicate Device	Manufacturer	Model	510(k) Control Number
	Mindray	DP-20/DP-30	K113153
2	Mindray	Z6	K122010
3	Mindray	M7	K121010

They have the same technological characteristics, are comparable in key safety and effectiveness features, and have the same intended uses and basic operating modes as the predicate devices.

The subject devices have been tested under IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-1-4, IEC 60601-2-37 and their software has been verified and validated.

These tests can support that the subject device is substantial equivalent to the predicate devices in aspect of safety and effectiveness.

6. Non-clinical Tests:

DP-20 and DP-30 Digital Ultrasonic Diagnostic Imaging System has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical safety standards. This device has been designed to meet the following standards: UEMA UD 2, UEMA UD 3, IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-1-4, IEC 60601-2-37,UL 60601-1, ISO14971 and ISO 10993-1, IEC 62366, IEC 62304.

7. Clinical Studies

Not applicable. The subject of this submission, DP-20 and DP-30 Digital Ultrasonic

K130833 Pye343

Diagnostic Imaging System, does not require clinical studies to support substantial equivelance.

Conclusion:

Intended uses and other key features are consistent with traditional clinical practices, FDA guidelines and established methods of patient examination. The design, development and quality process of the manufacturer confirms with 21 CFR 820, ISO 9001 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards. Therefore, the DP-20 and DP-30 Digital Ultrasonic Diagnostic Imaging System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.



Food and Drug Administration 10903 New Hampshire Avenue Document Control Center – WO66-G609 Silver Spring, MD 20993-0002

June 21, 2013

Shenzhen Mindray Bio-Medical Electronics Co., Ltd. % Susan D. Goldstein-Falk
Official Correspondent
MDI Consultants, Inc.
55 Northern Blvd., Suite 200
GREAT NECK NY 11021

Re: K130833

Trade/Device Name: DP-20/DP-30 Digital Ultrasonic Diagnostic Imaging System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: 11

Product Code: IYN, IYO, ITX

Dated: March 1, 2013 Received: March 26, 2013

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the DP-20/DP-30 Digital Ultrasonic Diagnostic Imaging System, as described in your premarket notification:

Transducer Model Number

35C20EA	35C50EB	65C15EA
65EC10EB	75L38EB	75L53EA
35C50EA	65EC10EA	75L38EA
101 24EA		

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safetv/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris

Director, Division of Radiological Health

for

Office of In Vitro Diagnostics

and Radiological Health

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130833 Device Name: DP-20 Digital Ultrasonic Diagnostic Imaging System DP-30 Digital Ultrasonic Diagnostic Imaging System Indications for Use: The Digital Ultrasonic Diagnostic Imaging System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, pediatric, small organ(breast, thyroid, testes), neonatal cephalic, adult cephalic, trans-rectal, musculo-skeletal (conventional, superficial), trans-vaginal, cardiac(adult, pediatric), peripheral vascular and urology exams. Prescription Use X AND/OR Over - The - Counter Use___ (21 CFR Part 807 Subpart C) (21 CFR Part 801 Subpart D) (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of In Vitro Diagnostic and Radiological Health (OIR) (Division Sign Off)

Division of Radiological Health

510(k) ___K130833___

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System	DP-20 Digital Ultrasonic Diagnostic Imaging System									
Model:		D	P-20		_					
510(k) Number(s)										
	Mode of Operation									
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)		
Ophthalmic										
Fetal	P	Р					P	Note1, Note 2		
Abdominal	Р	Р					Р	Note I, Note 2		
Intraoperative (specify)*			\vdash							
Intraoperative (Neuro)										
Laparoscopic										
Pediatric	Р	Р					Р.	Note I, Note 2		
Small organ(specify)**	Р	P					P	Note 2		
Neonatal Cephalic	Р	P					Р	Note 2		
Adult Cephalic	Р	P					Р	Note 2		
Trans-rectal	Р	Р					Р	Note 2		
Trans-veginal	Р	P					Р	Note 2		
Trans-urethral										
Trans-esoph.(non-Card.)										
Musculo-skeletal Conventional	þ	P					P	Note1, Note 2		
Musculo-skeletal Superficial	þ	P					Р	Note 2		
Intravascular										
Cardiac Adult	Р	P					P	Note 2		
Cardiac Pediatric	P	P					· P	Note 2		
Intravascular (Cardiac)										
Trans-esoph (Cardiac)										
Intra-Cardiac										
Peripheral Vascular	P	þ					Р	Note 2		
Other (specify)***	Р	Р				l	P	Note 1, Note 2		
N≖new indication; P=previously		•		ed under	Appendix	E				
Additional comments:Combi										
			, thyroic		ctc.					
			s Urolog		The Control	- daga				
	1: Tissue 2: Biops			aging.	ne jeatur	e does not i	use contrast	agents.		
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Concurrence of CDRH Off										

Transducer Model:				DP-20 Digital Ultrasonic Diagnostic Imaging System								
	35C20EA											
510(k) Number(s)							•					
					Mode of	Operation						
Clinical Application	В	Other (specify)										
Ophthalmic					Doppler	Doppler	(specify)					
Fetal												
Abdominal	Р	Р					Р	Note 2				
Intraoperative (specify)*			1									
Intraoperative (Neuro)												
Laparoscopic			1									
Pediatric	Р	Р					P	Note 2				
Small organ(specify)**			1									
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph (non-Card.)												
Musculo-skeletal Conventional	Ъ	Р					P ·	Note 2				
Musculo-skeletal Superficial												
Intravascular												
Cardiac Adult	P	P					P	Note 2				
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph.(Cardiac)												
Intra-Cardiac												
Peripheral Vascular	P	Р					P	Note 2				
Other (specify)***				•								
N=new indication; P=previously	cleared	by FD/	\: E=add	ed under	Appendix	E						
Additional comments:Combin												
			, thyroid		etc.							
			s Urolog									
				aging. T	he featur	e does not u	se contrast	agents.				
	: Biops			CONTEN	THE OST	ANOTHER	DACE IES	(EEDED)				
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Diag	gnostic	e Ultr	asoun	d Indi	cations	for Use F	orm.				
System		DP-20	Digital L	Itrasonic	Diagnosti	c Imaging Sy	/stem				
Transducer Model:		350	C50EB		-		•				
510(k) Number(s)					_						
p								***			
	Mode of Operation										
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)			
Ophthalmic											
Fetal	P	P					P	Note 1, Note 2			
Abdominal	P	P					P	Note1, Note 2			
Intraoperative (specify)*											
Intraoperative (Neuro)							-				
Laparoscopic											
Pediatric	P	P					P	Note1, Note 2			
Small organ(specify)**											
Neonatal Cephalic											
Adult Cephalic				-							
Trans-rectal											
Trans-vaginal											
Trans-urethral											
Trans-esoph.(non-Card.)											
Musculo-skeletal Conventional	P	P					P	Note I, Note 2			
Musculo-skeletal Superficial											
Intravascular											
Cardiac Adult											
Cardiac Pediatric											
Intravascular (Cardiac)											
Trans-esoph.(Cardiac)											
Intra-Cardiac											
Peripheral Vascular											
Other (specify)***	P	Р					Р	Note1, Note 2			
N=new indication; P=previously	cleared	by FD/	A; E=add	ed under	Appendix	E					
Additional comments: Combin	ned mo	des: B	÷М.								
			, thyroid	, testes,	etc.						
4404			- 11-1-								

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents. Note 2: Biopsy Guidance
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation(ODE)

System	DP-20 Digital Ultrasonic Diagnostic Imaging System								
Transducer Model:		650	C15EA		_				
510(k) Number(s)					_				
					Mode o	Operation			
Clinical Application	B M PWD CWD Color Doppler Doppler (specify) Other (spec								
Ophthalmic ·									
Fetal									
Abdominal	P	P					P	Note 2	
Intraoperative (specify)*									
Intraoperative (Neuro)									
Laparoscopic									
Pediatric	P	P					P	Note 2	
Small organ(specify)**									
Neonatal Cephalic	Р	P					P	Note 2	
Adult Cephalic	Р	Р					P	Note 2	
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph.(non-Card.)									
Musculo-skeletal Conventional	Р	P					P	Note 2	
Musculo-skeletal Superficial									
Intravascular									
Cardiac Adult									
Cardiac Pediatric	P	P					P	Note 2	
Intravascular (Cardiac)									
Trans-esoph (Cardiac)									
Intra-Cardiac									
Peripheral Vascular	P	P					р	Note 2	
Other (specify)***									
N=new indication; P=previously				ed under	Appendix	E.			
Additional comments:Combin	ned mod	des: B	+M.						
			, thyroid		etç.				
			s Urolog						
				aging. 1	he featur	e does not i	ase contrast	agents.	
Note 2 (PLEASE DO NOT WRITE I	: Biops			CONTU	MUE ON	ANOTHER	DAGETE	VEEDED)	
Concurrence of CDRH Offi						MOTHER	TAGE IF	TLEDED)	

Diag	znostic	e Ultr	asoun	d Indi	cations	for Use F	orm				
System		DP-20	Digital L	Itrasonic	Diagnosti	c Imaging St	stem				
Transducer Model:		65E	C10EB								
510(k) Number(s)					_			•			
	,										
	Mode of Operation										
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)			
Ophthalmic											
Fetal	P	Р					P	Note 2			
Abdominal .											
Intraoperative (specify)*			<u></u>								
Intraoperative (Neuro)											
Laparoscopic			L								
Pediatric											
Small organ(specify)**											
Neonatal Cephalic	P	P					Р	Note 2			
Adult Cephalic											
Trans-rectal	P	Р					Р	Note 2			
Trans-vaginal	Р	Р					Р	Note 2			
Trans-urethral											
Trans-esoph (non-Card.)											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Intravascular											
Cardiac Adult											
Cardiac Pediatric											
Intravascular (Cardiac)											
Trans-esoph (Cardiac)											
Intra-Cardiac											
Peripheral Vascular											
Other (specify)***	P	P					P	Note 2			
N=new indication; P=previously				ed under	Appendix	E					
Additional comments:Combi											
			, thyroid		etc.						
**Oth	er use in	nclude	s Urolog	y.							

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation(ODE)

Diag	,					for Use F					
System	-			Itrasonic	Diagnosti	c Imaging Sy	stem				
Transducer Model:		751	.38EB								
510(k) Number(s)					_						
	Mode of Operation										
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)			
Ophthalmic											
Fetal											
Abdominal	Р	P					P	Note 2			
Intraoperative (specify)*						I					
Intraoperative (Neuro)											
Laparoscopic											
Pediatric	P	P					P	Note 2			
Small organ(specify)**	Р	P			ł		P	Note 2			
Neonatal Cephalic	P	P					Р	Note 2			
Adult Cephalic								•			
Trans-rectal		L									
Trans-vaginal											
Trans-urethral											
Trans-esoph.(non-Card.)		<u> </u>									
Musculo-skeletal Conventional	Р	P					Р	Note 2			
Musculo-skeletal Superficial	P	Р					Р	Note 2			
Intravascular											
Cardiac Adult											
Cardiac Pediatric											
Intravascular (Cardiac)											
Trans-esoph.(Cardiac)											
Intra-Cardiac											
Peripheral Vascular	Р	Р					Р	Note 2			
Other (specify)***											
N=new indication; P=previously	cleared	by FD/	\; E=add	ed under	Appendix	E					
Additional comments:Combi											
			, thyroid	, testes,	etc.						
BACH.		lorde	. I Inclas								

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents. Note 2: Biopsy Guidance
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation(ODE)

System	•					c Imaging Sy		
Transducer Model:		751	.53EA					
510(k) Number(s)								
					Mode of	Operation		
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								•
Fetal								
Abdominal	P	Р					Р	Note 2
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P					Р	Note 2
Small organ(specify)**	P	p					Р	Note 2
Neonatal Cephalic	Р	P					P .	Note 2
Adult Cephalic								·
Trans-recia)								
Trans-veginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	P	P					P	Note 2
Musculo-skeletal Superficial	P	Ъ.					P	Note 2
Intravascular								
Cardiac Adult								•
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph (Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	Р					Р	Note 2
Other (specify)***								
N=new indication; P=previously	cleared	by FD/	\; E=add	ed under	Appendix	Е		
Additional comments:Combin								
			, thyroid		etc.			
			s Urolog					
Note I	: Tissu	e Harm	onic Im	aging. T	he featur	e does not u	ise contrast	agents.

Prescription USE (Per 21 CFR 801.109)

Note 2: Biopsy Guidance

Concurrence of CDRH, Office of Device Evaluation(ODE)

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System	nostic							
Model:			P-30			c Imaging Sy		
510(k) Number(s)								
					Mode of	Operation		
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	P	Р					Р '	Note 1, Note 2
Abdominal	Р	Р	1				Р	Note 1, Note 2
Intraoperative (specify)*			1					
Intraoperative (Neuro)								
l _e aparoscopic								
Pediatric	P	P		·			Р	Note I, Note 2
Small organ(specify)**	Р	Р					P	Note 2
Neonatal Cephalic	Р	P					P	Note 2
Adult Cephalic	P	Р					P	Note 2
Trans-rectal	P	Р					p ·	Note 2
Trans-vaginal	P	Р					P	Note 2
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeietal Conventional	Р	P					Р	Note I, Note 2
Musculo-skeletal Superficial	Р	P					Р	Note 2
Intravascular								
Cardiac Adult	P	P					Р	Note 2
Cardiac Pediatric	P	P					P	Note 2
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	Р	P					P	Note 2
Other (specify)***	P	Р					Р	Note1, Note 2
N=new indication; P=previously				ed under	Appendix	E		
Additional comments:Combin								
			, thyroic		etc.			
			s Urolog		TID. AV			
Note I	: Tissu	e Ha rn	nonic Im	aging. 3	he featur	e does not u	ise contrast	agents.

Note 2: Biopsy Guidance
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Prescription USE (Per 21 CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation(ODE)

System	DP-30 Digital Ultrasonic Diagnostic imaging System										
Transducer Model:		350	C20EA								
510(k) Number(s)					_						
							· · · · · · · · · · · · · · · · · · ·				
	Mode of Operation										
Clinical Application	B M PWD CWD Color Doppler Combined (specify) Other										
Ophthalmic											
Fetal				L							
Abdominal	P	Р					P	Note 2			
Intraoperative (specify)*											
Intraoperative (Neuro)											
Laparoscopic								•			
Pediatric	P	Р					P	Note 2			
Small organ(specify)**											
Neonatal Cephalic											
Adult Cephalic											
Trans-rectal											
Trans-vaginal											
Trans-urethral								·			
Trans-esoph.(non-Card.)											
Musculo-skeletal Conventional	P	P					Р	Note 2			
Musculo-skeletal Superficial											
Intravascular											
Cardiac Adult	P	P					P	Note 2			
Cardiac Pediatric											
Intravascular (Cardiac)											
Trans-esoph.(Cardiac)											
Intra-Cardiac											
Peripheral Vascular	P	Р					P	Note 2			
Other (specify)***											
N=new indication; P=previously	cleared	by FD	N; E=add	ed under	Appendix	E					
Additional comments:Combin	ned mo	des: B	+M.								
*Smal	l organ	-breast	, thyroid		etc.						
			s Urolog								
				aging. 1	The featur	e does not i	ise contrast	agents.			
	2: Biops			00)		4310777		icenen			
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Diag	gnostic	e Ultr	asoun	d Indi	cations	for Use F	orm					
System		DP-30	Digital L	Itrasonic	Diagnosti	c Imaging Sy	stem					
Transducer Model:		350	50EA		_							
510(k) Number(s)												
	Mode of Operation											
Clinical Application	B M PWD CWD Color Amplitude Combined Doppler (specify)							Other (specify)				
Ophthalmic												
Fetal	P	P					P	Note I, Note 2				
Abdominal	P	Р					P	Note I, Note 2				
Intraoperative (specify)*												
Intraoperative (Neuro)		<u> </u>										
Laparoscopic												
Pediatric	Р	P					Р	Note1, Note 2				
Small organ(specify)**												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral					1							
Trans-esoph (non-Card.)												
Musculo-skeletal Conventional	P	Р					Р	Note I, Note 2				
Musculo-skeletal Superficial												
Intravascular												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)						<u> </u>						
Trans-esoph (Cardiac)												
Intra-Cardiac					<u></u>							
Peripheral Vascular				L	<u> </u>							
Other (specify)***	Р	Р					Р	Note1, Note 2				
N=new indication; P=previously	cleared	by FD/	\; E=udd	ed under	Appendix	E						
Additional comments:Combi												
				l, testes,	etc.							
#*Oth	er use i	nelude	s Urolog	зу.								

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Diag	nostic	: Ultr	asoun	d India	cations	for Use K	Orm			
System		DP-30	Digital U	Itrasonic	Diagnosti	c Imaging Sy	/stem			
Transducer Model:		650	CISEA							
510(k) Number(s)										
,										
	Mode of Operation									
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)		
Ophthalmic										
Fetal										
Abdominal	P	P					Р	Note 2		
Intraoperative (specify)*						<u></u>				
Intraoperative (Neuro)										
Laparoscopic										
Pediatric	P	Р					Р	Note 2		
Small organ(specify)**										
Neonatal Cephalic	P	P					Р	Note 2		
Adult Cephalic	Р	ק					Р	Note 2		
Trans-rectal										
Trans-vaginal										
Trans-urethral										
Trans-esoph.(non-Card.)										
Musculo-skeletal Conventional	P	P					P	Note 2		
Musculo-skeletal Superficial										
Intravascular										
Cardiac Adult							•			
Cardiac Pediatric	P	Р					P	Note 2		
Intravascular (Cardiac)										
Trans-esoph.(Cardiac)										
Intra-Cardiac										
Peripheral Vascular	P	P					P	Note 2		
Other (specify)***										
N=new indication; P=previously	cleared	by FD/	A; E=add	ed under	Appendix	E				
Additional comments:Combin	ned mo	des: B	+M.							
*Small	l organ	-breast	, thyroic		etc.					
			s Uroloį							
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Transducer Model: 510(k) Number(s) Clinical Application	System	•					c Imaging Sy		
Clinical Application B M PWD CWD Color Doppler Combined (specify) Ophthalmic Fetal P P P P P P P P P P P P P P P P P P P	•						00,		
Clinical Application B M PWD CWD Color Doppler Amplitude Combined (specify) Other (specify) P P P P P P P P P P P P P P P P P P P	510(k) Number(s)					-			
Clinical Application B M PWD CWD Color Doppler Amplitude Combined (specify) Other (specify) P P P P P P P P P P P P P P P P P P P						•			
B M PWD CWD Doppler Doppler (specify) Ophthalmic Fetal P P P P P P P P P Note 2 Abdominal Intraoperative (specify)* Intraoperative (specify)* Intraoperative (Neuro) Laparoscopic Pediatric Small organ(specify)** Neonatal Cephalic P P P P P P P P P Note 2 Adult Cephalic P P P P P P P P P P Note 2 Trans-rectal P P P P P P P P P P Note 2 Trans-rectal P P P P P P P P P P Note 2 Trans-resph (non-Card.) Musculo-skeletal Conventional Musculo-skeletal Superficial Intravascular Cardiac Adult Cardiac Pediatric Intravascular (Cardiac) Trans-esoph (Cardiac) Peripheral Vascular Other (specify)*** P P P P P P P P Note 2 N=new indication, P=previously cleared by FDA; E=added under Appendix E Additional comments: Combined modes: B+M. *Small organ-breast, thyroid, testes, etc. **Other use includes Urology. Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents. Note 2: Biopsy Guidance				•		Mode of	f Operation		
Fetal P P P P Note 2 Abdominal Intrapperative (specify)* Intrapoperative (Neuro) Laparoscopic Pediatric Small organ(specify)** Neonatal Cephalic P P P P P P Note 2 Adult Cephalic Trans-rectal P P P P P P P Note 2 Irans-vaginal P P P P P P P P Note 2 Irans-vaginal P P P P P P P P Note 2 Irans-vaginal P P P P P P P P Note 2 Irans-vaginal P P P P P P P P P Note 2 Irans-vaginal P P P P P P P P Note 2 Irans-vaginal P P P P P P P P Note 2 Irans-vaginal P P P P P P P P Note 2 Irans-vaginal P P P P P P P P Note 2 Irans-vaginal P P P P P P P Note 2 Irans-vaginal P P P P P P P Note 2 Irans-vaginal P P P P P P P P Note 2 Irans-vaginal P P P P P P P P Note 2 Irans-coph (non-Card.) Intravascular-Cardiac P P P P P P P P Note 2 Irans-coph (Cardiac) Intra-Cardiac P P P P P P P P P Note 2 Irans-coph (Cardiac) Intra-Cardiac P P P P P P P P P Note 2 Irans-coph (Cardiac) Intra-Cardiac P P P P P P P P Note 2 Irans-coph (Cardiac) Intra-Cardiac P P P P P P P P Note 2 Irans-coph (Cardiac) Intra-Cardiac P P P P P P P P Note 2 Irans-coph (Cardiac) Intra-Cardiac P P P P P P P P Note 2 Irans-coph (Cardiac) Intra-Cardiac P P P P P P P P Note 2 Irans-coph (Cardiac) Intra-Cardiac P P P P P P P P Note 2 Irans-coph (Cardiac) Irans-coph (Car	Clinical Application	В	м	PWD	CWD				Other (specify)
Abdominal Intraoperative (specify)* Intraoperative (Neuro) Laparoscopic Pediatric Small organ(specify)** Neonatal Cephalic P P P P P P Note 2 Adult Cephalic Trans-rectal P P P P P P Note 2 Trans-vaginal P P P P P P Note 2 Trans-vaginal P P P P P P Note 2 Trans-vaginal Trans-esoph (non-Card.) Musculo-skeletal Conventional Musculo-skeletal Superficial Intravascular Cardiac Adult Cardiac Pediatric Intravascular (Cardiac) Trans-esoph (Cardiac) Intra-Cardiac Peripheral Vascular Other (specify)*** P P P P P P P P Note 2 Additional comments: Combined modes: B+M. *Small organ-breast, thyroid, testes, etc. **Other use includes Urology. Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents. Note 2: Biopsy Guidance	Ophthalmic								
Intraoperative (specify)* Intraoperative (Neuro) Laparoscopic Pediatric Small organ(specify)** Neonatal Cephalic P P P P P P P Note 2 Adult Cephalic Trans-rectal P P P P P P P Note 2 Trans-waginal P P P P P P Note 2 Trans-waginal P P P P P P P Note 2 Trans-wethral P P P P P P P Note 2 Trans-wethral P P P P P P P P Note 2 Trans-wethral P P P P P P P P P Note 2 Trans-esoph (non-Card.) P P P P P P P Note 2 Trans-esoph (conventional P P P P P P P P Note 2 Trans-esoph (Cardiac) P P P P P P P P Note 2 Trans-esoph (Cardiac) P P P P P P P Note 2 Trans-esoph (Cardiac) P P P P P P P Note 2 Trans-esoph (Cardiac) P P P P P P Note 2 Trans-esoph (Cardiac) P P P P P Note 2 Trans-esoph (Cardiac) P P P Note 2 Trans-esoph (Cardiac) P P P Note 2 Trans-esoph (Cardiac) P P P Note 2 Trans-esoph (Cardiac) P P P P Note 2 Trans-esoph (Car	Fetal	P	P					P	Note 2
Intraoperative (specify) Intraoperative (Neuro) Laparoscopic Pediatric Small organ(specify)** Neonatal Cephalic P P P P P P P Note 2 Adult Cephalic Trans-rectal P P P P P P P Note 2 Trans-vaginal P P P P P P P Note 2 Trans-unethral Trans-esoph (non-Card.) Musculo-skeletal Conventional Musculo-skeletal Superficial Intravascular Cardiac Adult Cardiac Pediatric Intravascular (Cardiac) Trans-esoph (Cardiac) Intra-Cardiac Peripheral Vascular Other (specify)*** P P P P P P P P Note 2 N=new indication, P=previously cleared by FDA; E=added under Appendix E Additional comments: Combined modes: B+M. *Small organ-breast, thyroid, testes, etc. **Other use includes Urology. Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents. Note 2: Biopsy Guidance	Abdominal								
Laparoscopic Pediatric Small organ(specify)** Neonatal Cephalic P P P P P P Note 2 Adult Cephalic Trans-rectal P P P P P P Note 2 Trans-vaginal P P P P P P P Note 2 Trans-urethral Trans-esoph (non-Card.) Musculo-skeletal Conventional Musculo-skeletal Superficial Intravascular Cardiac Adult Cardiac Pediatric Intravascular (Cardiac) Trans-esoph (Cardiac) Intra-cardiac Peripheral Vascular Other (specify)*** P P P P P P P Note 2 N=new indication, P=previously cleared by FDA; E=added under Appendix E Additional comments: Combined modes: B+M. *Small organ-breast, thyroid, testes, etc. **Other use includes Urology. Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents. Note 2: Biopsy Guidance	Intraoperative (specify)*							,	
Pediatric Small organ(specify)** Neonatal Cephalic P P P P P P Note 2 Adult Cephalic Trans-rectal P P P P P P Note 2 Trans-vaginal P P P P P P Note 2 Trans-vaginal Trans-esoph (non-Card.) Musculo-skeletal Conventional Musculo-skeletal Superficial Intravascular Cardiac Adult Cardiac Pediatric Intravascular (Cardiac) Trans-esoph (Cardiac) Intra-Cardiac Peripheral Vascular Other (specify)*** P P P P P P Note 2 Additional comments: Combined modes: B+M. *Small organ-breast, thyroid, testes, etc. **Other use includes Urology. Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents. Note 2: Biopsy Guidance	Intraoperative (Neuro)								
Small organ(specify)** Neonatal Cephalic P P P Note 2 Adult Cephalic Trans-rectal P P P Note 2 Trans-vaginal P P P Note 2 Trans-vaginal Trans-restph (non-Card.) Musculo-skeletal Conventional Musculo-skeletal Superficial Intravascular Cardiac Adult Cardiac Pediatric Intravascular (Cardiac) Intravascular (Cardiac) Intravascular (Cardiac) Peripheral Vascular Other (specify)*** P P P Note 2 Additional comments: Combined modes: B+M. *Small organ-breast, thyroid, testes, etc. **Other use includes Urology. Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents. Note 2: Biopsy Guidance	Laparoscopic								
Neonatal Cephalic Adult Cephalic Trans-rectal P P P P P P P P P P P P P P P P P P	Pediatric								
Adult Cephalic Trans-rectal P P P P P Note 2 Trans-vaginal P P P P P Note 2 Trans-urethral Trans-esoph (non-Card.) Musculo-skeletal Conventional Musculo-skeletal Superficial Intravascular Cardiac Adult Cardiac Pediatric Intravascular (Cardiac) Trans-esoph (Cardiac) Trans-esoph (Cardiac) Trans-esoph (Cardiac) Trans-esoph (Cardiac) Note (specify)*** P P P P P Note 2 N=new indication; P=previously cleared by FDA; E=added under Appendix E Additional comments: Combined modes: B+M. *Small organ-breast, thyroid, testes, etc. **Other use includes Urology. Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents. Note 2: Biopsy Guidance	Small organ(specify)**								
Trans-rectal P P P Note 2 Trans-vaginal P P P Note 2 Trans-urethral P P P Note 2 Trans-esoph.(non-Card.) Musculo-skeletal Conventional Musculo-skeletal Superficial Intravascular Cardiac Adult Cardiac Intravascular Cardiac Adult Cardiac Pediatric Intravascular (Cardiac) Trans-esoph.(Cardiac) Trans-esoph.(Cardiac) Trans-esoph.(Cardiac) Peripheral Vascular Other (specify)*** P P P Note 2 N=new indication, P=previously cleared by FDA; E=added under Appendix E Additional comments:Combined modes: B+M. *Small organ-breast, thyroid, testes, etc. **Other use includes Urology. Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents. Note 2: Biopsy Guidance	Neonatal Cephalic	P	Р					Р	Note 2
Trans-vaginal P P Note 2 Trans-urethral	Adult Cephalic								
Trans-esoph.(non-Card.) Musculo-skeletal Conventional Musculo-skeletal Superficial Intravascular Cardiac Adult Cardiac Pediatric Intravascular (Cardiac) Trans-esoph.(Cardiac) Intra-Cardiae Peripheral Vascular Other (specify)*** P P Note 2 Additional comments: Combined modes: B+M. *Small organ-breast, thyroid, testes, etc. **Other use includes Urology. Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents. Note 2: Biopsy Guidance	Trans-rectal	P	Р					P	Note 2
Trans-esoph.(non-Card.) Musculo-skeletal Conventional Musculo-skeletal Superficial Intravascular Cardiac Adult Cardiac Pediatric Intravascular (Cardiac) Trans-esoph.(Cardiac) Intra-Cardiac Peripheral Vascular Other (specify)*** P P Note 2 Additional comments: Combined modes: B+M. *Small organ-breast, thyroid, testes, etc. **Other use includes Urology. Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents. Note 2: Biopsy Guidance	Trans-vaginal	Р	Р					Р	Note 2
Musculo-skeletal Conventional Musculo-skeletal Superficial Intravascular Cardiac Adult Cardiac Pediatric Intravascular (Cardiac) Intravascular (Cardiac) Intra-Cardiac Peripheral Vascular Other (specify)*** P P P Note 2 M=new indication, P=previously cleared by FDA; E=added under Appendix E Additional comments: Combined modes: B+M. *Small organ-breast, thyroid, testes, etc. **Other use includes Urology. Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents. Note 2: Biopsy Guidance	Trans-urethral								
Musculo-skeletal Superficial Intravascular Cardiac Adult Cardiac Pediatric Intravascular (Cardiac) Trans-esoph.(Cardiac) Intra-Cardiac Peripheral Vascular Other (specify)*** P P P Note 2 M=new indication; P=previously cleared by FDA; E=added under Appendix E Additional comments: Combined modes: B+M. *Small organ-breast, thyroid, testes, etc. **Other use includes Urology. Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents. Note 2: Biopsy Guidance	Trans-esoph.(non-Card.)								
Intravascular Cardiac Adult Cardiac Pediatric Intravascular (Cardiac) Intravascular (Cardiac) Intra-Cardiac Intra-Cardiac Peripheral Vascular Other (specify)*** PPP PNote 2 Additional comments: Combined modes: B+M. *Small organ-breast, thyroid, testes, etc. **Other use includes Urology. Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents. Note 2: Biopsy Guidance	Musculo-skeletal Conventional								
Cardiac Adult Cardiac Pediatric Intravascular (Cardiac) Trans-esoph.(Cardiac) Intra-Cardiac Intra-Cardiac Peripheral Vascular Other (specify)*** PPP PNote 2 N=new indication; P=previously cleared by FDA; E=added under Appendix E Additional comments: Combined modes: B+M. *Small organ-breast, thyroid, testes, etc. **Other use includes Urology. Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents. Note 2: Biopsy Guidance	Musculo-skeletal Superficial			ì					
Cardiac Pediatric Intravascular (Cardiac) Trans-esoph.(Cardiac) Intra-Cardiac Peripheral Vascular Other (specify)*** PPP PNote 2 N=new indication; P=previously cleared by FDA; E=added under Appendix E Additional comments: Combined modes: B+M. *Small organ-breast, thyroid, testes, etc. **Other use includes Urology. Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents, Note 2: Biopsy Guidance	Intravascular								
Intravascular (Cardiac) Trans-esoph (Cardiac) Intra-Cardiae Peripheral Vascular Other (specify)*** P P P Note 2 N=new indication; P=previously cleared by FDA; E=added under Appendix E Additional comments: Combined modes: B+M. *Small organ-breast, thyroid, testes, etc. **Other use includes Urology. Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents. Note 2: Biopsy Guidance	Cardiac Adult								
Trans-esoph (Cardiac) Intra-Cardiae Peripheral Vascular Other (specify)*** P P P P Note 2 N=new indication; P=previously cleared by FDA; E=added under Appendix E Additional comments: Combined modes: B+M. *Small organ-breast, thyroid, testes, etc. **Other use includes Urology. Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents. Note 2: Biopsy Guidance	Cardiac Pediatric								
Intra-Cardiac Peripheral Vascular Other (specify)*** P P P P Note 2 N=new indication; P=previously cleared by FDA; E=added under Appendix E Additional comments: Combined modes: B+M. *Small organ-breast, thyroid, testes, etc. **Other use includes Urology. Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents. Note 2: Biopsy Guidance	Intravascular (Cardiac)								
Peripheral Vascular Other (specify)*** P P P P Note 2 N=new indication; P=previously cleared by FDA; E=added under Appendix E Additional comments: Combined modes: B+M. *Small organ-breast, thyroid, testes, etc. **Other use includes Urology. Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents. Note 2: Biopsy Guidance	Trans-esoph (Cardiac)								
Other (specify)*** P P P P P Note 2 N=new indication; P=previously cleared by FDA; E=added under Appendix E Additional comments: Combined modes: B+M. *Small organ-breast, thyroid, testes, etc. **Other use includes Urology. Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents. Note 2: Biopsy Guidance	Intra-Cardiac								
N=new indication; P=previously cleared by FDA; E=added under Appendix E Additional comments: Combined modes: B+M. *Small organ-breast, thyroid, testes, etc. **Other use includes Urology. Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents. Note 2: Biopsy Guidance	Peripheral Vascular								
Additional comments: Combined modes: B+M. *Small organ-breast, thyroid, testes, etc. **Other use includes Urology. Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents. Note 2: Biopsy Guidance	Other (specify)***	P	Р					Р	Note 2
*Small organ-breast, thyroid, testes, etc. **Other use includes Urology. Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents. Note 2: Biopsy Guidance	N=new indication; P=previously	cleared	by FD/	N; E≃add	ed under	Appendix	E	, ,	
**Other use includes Urology. Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents. Note 2: Biopsy Guidance	Additional comments:Combin	ned mo	des: B	+M.					
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents. Note 2: Biopsy Guidance	•Smal	l organ	-breast	, thyroid	, testes,	etc.			
Note 2: Biopsy Guidance									
					aging. T	he featur	e does not u	ise contrast	agents.
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System		DP-30	Digital U	ijrasonic	Diagnosii	c imaging 5)	/siem	
Transducer Model:		75	L38EA					
510(k) Number(s)								
					Mode o	f Operation		
Clinical Application	Color Amelitude Com							
- The state of the	В	М	PWD	CWD	Doppler	Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	P	P					P	Note 2
Intraoperative (specify)*								•
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P					P	Note 2
Small organ(specify)**	P	P					P	Note 2
Neonatal Cephalic	P	P					P	Note 2
Adult Cephalic								
Trans-rectal								4
Trans-vaginal							•	
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	Р	P					P	Note 2
Musculo-skeletal Superficial	Р	P					P	Note 2
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	P					P	Note 2
Other (specify)***								
N=new indication; P=previously	cleared	by FD/	A; E=adde	ed under	Appendix	E.		
Additional comments:Combin	red mor	des: B	+М.		-			
**Sma	ili organ	n-brca:	st, thyroi		, etc.			
			es Urolo					
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System		DP-30	Digital U	ltrasonic	Diagnosti	c Imaging Sy	slem	
Transducer Model:		751	.53EA					
510(k) Number(s)								
	Mode of Operation							
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
A bdominal	P	Р					Р	Note 2
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P					P	Note 2
Small organ(specify)**	P	Ъ					P	Note 2
Neonatal Cephalic	P	P			_ 1		P	Note 2
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	P	P					P	Note 2
Musculo-skeletal Superficial	P	P					Р	Note 2
Intravascular								
Cardiac Adult								
Cardiae Pediatric								
Intravascular (Cardiac)								
Trans-esoph (Cardiac)								
Intra-Cardiac								
Peripheral Vascular	Р	P					Ρ.	Note 2
Other (specify)***								
N=new indication; P=previously			-	ed under	Appendix	E		
Additional comments:Combin								
			, thyroid		etc.			
			s Urolog		P1 0	•		
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System				THE US COME	D. (a.B.) (O.) (1	c imaging o	310111		
Transducer Model:		101	L24EA						
510(k) Number(s)					-				
Oliciael Acadianian	Mode of Operation								
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)	
Ophthalmic									
Fetal									
Abdominal									
Intraoperative (specify)*									
Intraoperative (Neuro)									
Laparoscopic									
Pediatric									
Small organ(specify)**	Р	P					P	Note 2	
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral				L					
Trans-esoph.(non-Card.)									
Musculo-skeletal Conventional	P	Р					P	Note 2	
Musculo-skeletal Superficial	P	P					P	Note 2	
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph (Cardiac)									
Intra-Cardiac									
Peripheral Vascular	P	P					P	Note 2	
Other (specify)***			<u> </u>		<u> </u>	<u> </u>			
N=new indication; P=previously	cleared	by FD	A; E=add	ed under	Appendix	Е			
Additional comments:Combin	ned mo	des: B	+M.	,					
			, thyroic		etc.				
			s Urolo						
	_			naging.	The featur	re does not	use contrast	agents.	
Note 2	2: Biops	y Gui	dance	CONT	NUIE ON	AMOTUE	DACETE	VICEDEDI	
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Concurrence of CDRH, Off	ice oi l	Serice	Evalua	טטאנטט	(2)				